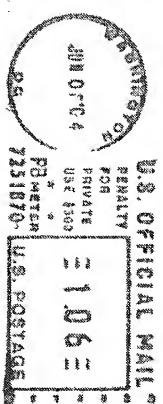


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APPL NO.	FILING OR 371 (c) DATE	ART UNIT	FIL FEE REC'D	ATTY.DOCKET NO	DRAWINGS	TOT CLMS	IND CLMS
10/728,420	12/05/2003	1645	3954	122294-1010	22	87	26

CONFIRMATION NO. 8619

GARDERE WYNNE SEWELL LLP
Suite 3400
1000 Louisiana
Houston, TX 77002

FILING RECEIPT



OC000000012900497

Date Mailed: 06/08/2004

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please write to the Office of Initial Patent Examination's Filing Receipt Corrections, facsimile number 703-746-9195. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

Applicant(s)

Susan L. Woulfe, Manchester, MO;
Rita Jain, Roslyn Harbor, NY;
Aimee Burr, Chicago, IL;

Domestic Priority data as claimed by applicant

This appln claims benefit of 60/431,053 12/05/2002

Foreign Applications

If Required, Foreign Filing License Granted: 06/08/2004

Projected Publication Date: To Be Determined - pending completion of Missing Parts

Non-Publication Request: No

Early Publication Request: No

Title

Engineered Fab' fragment anti-tumor necrosis factor alpha in combination with disease modifying anti-rheumatic drugs

**LICENSE FOR FOREIGN FILING UNDER
Title 35, United States Code, Section 184
Title 37, Code of Federal Regulations, 5.11 & 5.15**

GRANTED

The applicant has been granted a license under 35 U.S.C. 184, if the phrase "IF REQUIRED, FOREIGN FILING LICENSE GRANTED" followed by a date appears on this form. Such licenses are issued in all applications where the conditions for issuance of a license have been met, regardless of whether or not a license may be required as set forth in 37 CFR 5.15. The scope and limitations of this license are set forth in 37 CFR 5.15(a) unless an earlier license has been issued under 37 CFR 5.15(b). The license is subject to revocation upon written notification. The date indicated is the effective date of the license, unless an earlier license of similar scope has been granted under 37 CFR 5.13 or 5.14.

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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/728,420	12/05/2003	Susan L. Woulfe	122294-1010

CONFIRMATION NO. 8619

GARDERE WYNNE SEWELL LLP
Suite 3400
1000 Louisiana
Houston, TX 77002

FORMALITIES LETTER



OC00000012900498

Date Mailed: 06/08/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

For questions regarding compliance to these requirements, please contact:

- For Rules Interpretation, call (703) 308-4216
- To Purchase PatentIn Software, call (703) 306-2600
- For PatentIn Software Program Help, call (703) 306-4119 or e-mail at patin21help@uspto.gov or patin3help@uspto.gov

SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is **\$130** for a Large Entity

- \$130 Late oath or declaration Surcharge.

Replies should be mailed to: Mail Stop Missing Parts
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PART 1 - ATTORNEY/APPLICANT COPY



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APPLICATION NUMBER	FILING OR 371 (c) DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NUMBER
10/728,420	12/05/2003	Susan L. Woulfe	122294-1010

GARDERE WYNNE SEWELL LLP
Suite 3400
1000 Louisiana
Houston, TX 77002

CONFIRMATION NO. 8619

FORMALITIES LETTER



OC00000012900498

Date Mailed: 06/08/2004

NOTICE TO FILE MISSING PARTS OF NONPROVISIONAL APPLICATION

FILED UNDER 37 CFR 1.53(b)

Filing Date Granted

Items Required To Avoid Abandonment:

An application number and filing date have been accorded to this application. The item(s) indicated below, however, are missing. Applicant is given **TWO MONTHS** from the date of this Notice within which to file all required items and pay any fees required below to avoid abandonment. Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a).

- The oath or declaration is unsigned.
- To avoid abandonment, a late filing fee or oath or declaration surcharge as set forth in 37 CFR 1.16(e) of \$130 for a non-small entity, must be submitted with the missing items identified in this letter.
- A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 CFR 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing." Applicant must provide a substitute computer readable form (CRF) copy of the "Sequence Listing" and a statement that the content of the sequence listing information recorded in computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b), or 1.825(d).

For questions regarding compliance to these requirements, please contact:

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SUMMARY OF FEES DUE:

Total additional fee(s) required for this application is \$130 for a Large Entity

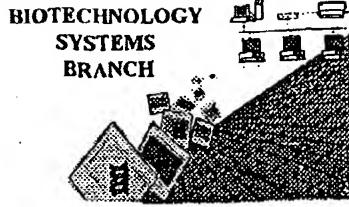
- \$130 Late oath or declaration Surcharge.

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PART 2 - COPY TO BE RETURNED WITH RESPONSE



RAW SEQUENCE LISTING ERROR REPORT

The Biotechnology Systems Branch of the Scientific and Technical Information Center (STIC) detected errors when processing the following computer readable form:

Application Serial Number: 10/728,420
Source: 1F610
Date Processed by STIC: 8/28/04

THE ATTACHED PRINTOUT EXPLAINS DETECTED ERRORS.

PLEASE FORWARD THIS INFORMATION TO THE APPLICANT BY EITHER:

- 1) INCLUDING A COPY OF THIS PRINTOUT IN YOUR NEXT COMMUNICATION TO THE APPLICANT, WITH A NOTICE TO COMPLY or,
- 2) TELEPHONING APPLICANT AND FAXING A COPY OF THIS PRINTOUT, WITH A NOTICE TO COMPLY

FOR CRF SUBMISSION AND PATENTIN SOFTWARE QUESTIONS, PLEASE CONTACT MARK SPENCER, TELEPHONE: 571-272-2510; FAX: 571-273-0221

TO REDUCE ERRORED SEQUENCE LISTINGS, PLEASE USE THE **CHECKER VERSION 4.2 PROGRAM**, ACCESSIBLE THROUGH THE U.S. PATENT AND TRADEMARK OFFICE WEBSITE. SEE BELOW FOR ADDRESS:

<http://www.uspto.gov/web/offices/pac/checker/chkrnote.htm>

Applicants submitting genetic sequence information electronically on diskette or CD-Rom should be aware that there is a possibility that the disk/CD-Rom may have been affected by treatment given to all incoming mail.

Please consider using alternate methods of submission for the disk/CD-Rom or replacement disk/CD-Rom.

Any reply including a sequence listing in electronic form should NOT be sent to the 20231 zip code address for the United States Patent and Trademark Office, and instead should be sent via the following to the indicated addresses:

1. EFS-Bio (<http://www.uspto.gov/dbc/efs/downloads/documents.htm>), EFS Submission User Manual - ePAVE)
2. U.S. Postal Service: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450
3. Hand Carry, Federal Express, United Parcel Service, or other delivery service (EFFECTIVE 06/05/04):
U.S. Patent and Trademark Office, 220 20th Street S., Customer Window, Mail Stop Sequence, Crystal Plaza Two, Lobby, Room 1B03, Arlington, VA 22202

Revised 05/17/04

Raw Sequence Listing Error Summary

<u>ERROR DETECTED</u>	<u>SUGGESTED CORRECTION</u>	<u>SERIAL NUMBER:</u> <u>10/128,420</u>
ATTN: NEW RULES CASES: PLEASE DISREGARD ENGLISH "ALPHA" HEADERS, WHICH WERE INSERTED BY PTO SOFTWARE		
1 <input type="checkbox"/> Wrapped Nucleic	The number/text at the end of each line "wrapped" down to the next line. This may occur if your file was retrieved in a word processor after creating it. Please adjust your right margin to .3; this will prevent "wrapping."	
2 <input type="checkbox"/> Invalid Line Length	The rules require that a line not exceed 72 characters in length. This includes white spaces.	
3 <input type="checkbox"/> Misaligned Amino Numbering	The numbering under each 5 th amino acid is misaligned. Do not use tab codes between numbers; use space characters, instead.	
4 <input type="checkbox"/> Non-ASCII	The submitted file was not saved in ASCII(DOS) text, as required by the Sequence Rules. Please ensure your subsequent submission is saved in ASCII text.	
5 <input type="checkbox"/> Variable Length	Sequence(s) _____ contain n's or Xaa's representing more than one residue. Per Sequence Rules, each n or Xaa can only represent a single residue. Please present the maximum number of each residue having variable length and indicate in the <220>-<223> section that some may be missing.	
6 <input type="checkbox"/> PatentIn 2.0 "bug"	A "bug" in PatentIn version 2.0 has caused the <220>-<223> section to be missing from amino acid sequences(s) _____. Normally, PatentIn would automatically generate this section from the previously coded nucleic acid sequence. Please manually copy the relevant <220>-<223> section to the subsequent amino acid sequence. This applies to the mandatory <220>-<223> sections for Artificial or Unknown sequences.	
7 <input type="checkbox"/> Skipped Sequences (OLD RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence: (2) INFORMATION FOR SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) (i) SEQUENCE CHARACTERISTICS: (Do not insert any subheadings under this heading) (ii) SEQUENCE DESCRIPTION:SEQ ID NO:X: (insert SEQ ID NO where "X" is shown) This sequence is intentionally skipped Please also adjust the "(ii) NUMBER OF SEQUENCES:" response to include the skipped sequences.	
8 <input type="checkbox"/> Skipped Sequences (NEW RULES)	Sequence(s) _____ missing. If intentional, please insert the following lines for each skipped sequence. <210> sequence id number <400> sequence id number 000	
9 <input type="checkbox"/> Use of n's or Xaa's (NEW RULES)	Use of n's and/or Xaa's have been detected in the Sequence Listing. Per 1.823 of Sequence Rules, use of <220>-<223> is MANDATORY if n's or Xaa's are present. In <220> to <223> section, please explain location of n or Xaa, and which residue n or Xaa represents.	
10 <input type="checkbox"/> Invalid <213> Response	Per 1.823 of Sequence Rules, the only valid <213> responses are: Unknown, Artificial Sequence, or scientific name (Genus/species). <220>-<223> section is required when <213> response is Unknown or is Artificial Sequence	
11 <input type="checkbox"/> Use of <220>	Sequence(s) _____ missing the <220> "Feature" and associated numeric identifiers and responses. Use of <220> to <223> is MANDATORY if <213> "Organism" response is "Artificial Sequence" or "Unknown." Please explain source of genetic material in <220> to <223> section. (See "Federal Register," 06/01/1998, Vol. 63, No. 104, pp. 29631-32) (Sec. 1.823 of Sequence Rules)	
12 <input type="checkbox"/> PatentIn 2.0 "bug"	Please do not use "Copy to Disk" function of PatentIn version 2.0. This causes a corrupted file, resulting in missing mandatory numeric identifiers and responses (as indicated on raw sequence listing). Instead, please use "File Manager" or any other manual means to copy file to floppy disk.	
13 <input type="checkbox"/> Misuse of n/Xaa	"n" can only represent a single nucleotide; "Xaa" can only represent a single amino acid	



IFWO

RAW SEQUENCE LISTING

PATENT APPLICATION: US/10/728,420

DATE: 05/28/2004

TIME: 13:16:24

Input Set : D:\Sequence Listing.txt
 Output Set: N:\CRF4\05282004\J728420.raw

4 <110> APPLICANT: WOULFE, SUSAN L.
 5 JAIN, RITA
 6 BURR, AIMEE
 8 <120> TITLE OF INVENTION: ENGINEERED FAB' FRAGMENT ANTI-TUMOR
 9 NECROSIS FACTOR ALPHA IN COMBINATION WITH DISEASE MODIFYING
 10 ANTI-RHEUMATIC DRUGS
 12 <130> FILE REFERENCE: 122294-1010
 -> 14 <140> CURRENT APPLICATION NUMBER: US/10/728,420
 16 <141> CURRENT FILING DATE: 2003-12-05
 18 <150> PRIOR APPLICATION NUMBER: US 60/431,053
 20 <151> PRIOR FILING DATE: 2002-12-05
 22 <160> NUMBER OF SEQ ID NOS: 40 *(see following pages)*
 24 <170> SOFTWARE: FastSEQ for Windows Version 4.0

STORED SEQUENCES

-> 164 <210> SEQ ID NO: 11 *see following pages*
 -> 201 <210> SEQ ID NO: 83
 424 <210> SEQ ID NO: 98
 425 <211> LENGTH: 11 *12 shown below*
 426 <212> TYPE: PRT
 427 <213> ORGANISM: Artificial Sequence
 429 <220> FEATURE:
 430 <223> OTHER INFORMATION: human group 1 consensus framework H4
 432 <400> SEQUENCE: 98
 433 Trp Gly Gln Gly Thr Thr Leu Val Thr Val Ser Ser
 -> 434 1 5 10
 -> 691 <210> SEQ ID NO: 113 *see following pages*
 -> 730 <210> SEQ ID NO: 115

Does Not Comply
 Corrected Diskette Needed

RAW SEQUENCE LISTING ERROR SUMMARY
PATENT APPLICATION: US/10/728,420

DATE: 05/28/2004
TIME: 13:16:26

Input Set : D:\Sequence Listing.txt
Output Set: N:\CRF4\05282004\J728420.raw

IMPORTANT

Skipped Sequences (NEW RULES):

Sequence(s) missing. If intentional, please use the following format for each skipped sequence.

<210> sequence id number
<400> sequence id number
000

Seq#:9,10,12,13,14,15,16,17,18,19,20,21,22,23,24,25,26,27,28,29,30,31,32,33,34

Seq#:35,36,37,38,39,40,41,42,43,44,45,46,47,48,49,50,51,52,53,54,55,56,57,58

Seq#:59,60,61,62,63,64,65,66,67,68,69,70,71,72,73,74,75,76,77,78,79,80,81,82

Seq#:110,111,112,114/

The above sequences are missing. If intentionally skipped, please use the above format exactly.

(See p.3 for a sample of missing sequences)

10/928,420 3

<400> 8
gac att caa atg acc cag agc cca tcc agc ctg agc gca tct gta gga 48
Asp Ile Gln Met Thr Gln Ser Pro Ser Ser Leu Ser Ala Ser Val Gly
1 5 10 15

gac cgg gtc acc atc act tgt aaa gcc agt cag aac gta ggt act aac 96
Asp Arg Val Thr Ile Thr Cys Lys Ala Ser Gln Asn Val Gly Thr Asn
20 25 30

gta gcc tgg tat cag caa aaa cca ggt aaa gcc cca aaa gcc ctc atc 144
Val Ala Trp Tyr Gln Gln Lys Pro Gly Lys Ala Pro Lys Ala Leu Ile
35 40 45

tac agt gcc tct ttc ctc tat agt ggt gta cca tac agg ttc agc gga 192
Tyr Ser Ala Ser Phe Leu Tyr Ser Gly Val Pro Tyr Arg Phe Ser Gly
50 55 60

tcc ggt agt ggt act gat ttc acc ctc acg atc agt agc ctc cag cca 240
Ser Gly Ser Gly Thr Asp Phe Thr Leu Thr Ile Ser Ser Leu Gln Pro
65 70 75 80

gaa gat ttc gcc act tat tac tgt caa cag tat aac atc tac cca ctc 288
Glu Asp Phe Ala Thr Tyr Tyr Cys Gln Gln Tyr Asn Ile Tyr Pro Leu
85 90 95

aca ttc ggt cag ggt act aaa gta gaa atc aaa 321
Thr Phe Gly Gln Gly Thr Lys Val Glu Ile Lys
100 105

Sequences 9 and 10 are missing

<210> 11

see p. 4

10/728,420 4

<210> 1
<211> 5
<212> PRT
<213> Artificial Sequence

<220>
<223> hTNF40 CDRH1

? please give source of genetic material

Please connect any subsequent sequences
with this type of explanation:

See item 11 on Error Summary Sheet.

VERIFICATION SUMMARY

PATENT APPLICATION: US/10/728,420

DATE: 05/28/2004

TIME: 13:16:26

Input Set : D:\Sequence Listing.txt
Output Set: N:\CRF4\05282004\J728420.raw

14 M:270 C: Current Application Number differs, Replaced Application Number
134 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:8
164 M:216 E: (34) Seq.#s missing, SEQ ID NOS: 9 thru 10
177 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:11
?11 M:216 E: (34) Seq.#s missing, SEQ ID NOS: 12 thru 82
134 M:252 E: No. of Seq. differs, <211> LENGTH:Input:11 Found:12 SEQ:98
?29 M:281 W: Numeric Fields not Ordered, <221> Sort in ascending order!
?33 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:101
?52 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:102
?76 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:103
?00 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:104
?24 M:258 W: Mandatory Feature missing, <220> Tag not found for SEQ ID#:105
?91 M:216 E: (34) Seq.#s missing, SEQ ID NOS: 110 thru 112
?30 M:214 E: (33) Seq.# missing, SEQ ID NO:114